

**LISTING OF CLAIMS:**

1-61. (Cancelled)

62. (Previously presented) A composition comprising: an isolated HIV Tat protein in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein is biologically active, as shown by (1) the ability of said isolated HIV Tat protein to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml; and (2) the ability of said isolated HIV Tat protein to do one or both of the following (i) and (ii):

- (i) enter and localize in the nuclei of activated endothelial cells or dendritic cells, which entering and localizing is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy; or
- (ii) activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein is present at a concentration of up to 1 µg/ml,

wherein said composition is pharmaceutically acceptable for administration to a human.

63. (Previously presented) The composition of claim 62, wherein said isolated HIV Tat protein is purified.

64. (Cancelled)

65. (Previously presented) The composition of claim 62, wherein said isolated HIV Tat protein is a wild type HIV Tat protein.

66. (Previously presented) The composition of claim 62, 63 or 65, wherein the administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.
67. (Cancelled)
68. (Previously presented) The composition of claim 63, wherein said isolated HIV Tat protein is purified by a method comprising performing heparin affinity chromatography.
69. (Previously presented) The composition of claim 68, wherein said performing step is followed by steps of (a) lyophilizing said isolated HIV Tat protein, and (b) resuspending said lyophilized isolated HIV Tat protein in a degassed buffer.
- 70-88. (Cancelled)
89. (Previously presented) The composition of claim 62, 63 or 65 which further comprises a biologically acceptable fluid.
90. (Previously presented) A product which is produced by a process comprising lyophilizing the composition of claim 62, 63 or 65.
91. (Previously presented) A product which is produced by a process comprising lyophilizing the composition of claim 62, 63 or 65 and resuspending the lyophilized composition in a biologically acceptable fluid.
92. (Previously presented) The composition of claim 65, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.
93. (Previously presented) The composition of claim 89, wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
94. (Previously presented) The product of claim 91, wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
95. (Previously presented) The composition of claim 62, 63, 65, or 69 which further comprises an adjuvant.

96. (Previously presented) The composition of claim 95 which further comprises a biologically acceptable fluid.
97. (Previously presented) The composition of claim 95, wherein the adjuvant is RIBI, alum, or ISCOM, or a combination thereof.
98. (Previously presented) The composition of claim 62, 63 or 65, wherein said isolated HIV Tat protein is bound to a delivery vehicle.
99. (Previously presented) The composition of claim 98, wherein said delivery vehicle is a nanoparticle.
100. (Previously presented) The composition of claim 98, wherein said delivery vehicle is an autologous erythrocyte.
101. (Previously presented) The composition of claim 66, wherein the administration is systemic.
102. (Previously presented) The composition of claim 66, wherein the administration is intradermal.
103. (Previously presented) The composition of claim 66, wherein the administration is subcutaneous.
104. (Cancelled)
105. (Previously presented) The composition of claim 66, wherein the administration is mucosal.
106. (Previously presented) The composition of claim 95, wherein the administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.
107. (Previously presented) The composition of claim 106, wherein the administration is systemic.
108. (Previously presented) The composition of claim 106, wherein the administration is intradermal.

109. (Previously presented) The composition of claim 106, wherein the administration is subcutaneous.

110. (Previously presented) The composition of claim 109 which further comprises Alum.

111. (Previously presented) The composition of claim 106, wherein the administration is mucosal

112. (Previously presented) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein is conjugated to a T-helper peptide or T-helper universal epitope of Tetanus Toxoid.

113. (Cancelled)

114. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises HIV rev, nef or gag, or an immunogenic fragment thereof.

115. (Cancelled)

116. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises an immuno-modulant cytokine.

117. (Previously presented) The composition of claim 116, wherein said immuno-modulant cytokine is IL-12 or IL-15.

118. (Cancelled)

119. (Previously presented) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein is fused to HIV rev, nef or gag, or an immunogenic fragment thereof.

120. (Cancelled)

121. (Previously presented) The composition of claim 62, 63, 65, or 69, wherein said isolated HIV Tat protein is fused to an immuno-modulant cytokine.

122. (Previously presented) The composition of claim 121, wherein said immuno-modulant cytokine is IL-12 or IL-15.

123. (Previously presented) The composition of claim 62, 63, 65, or 69, which further comprises an inhibitor of viral replication.

124-141. (Cancelled)

142. (Previously presented) The composition of claim 62 which comprises a combination of said isolated HIV Tat protein.

143. (Previously presented) The composition of claim 62 or 63 which is suitable for inducing an immune response in the human to said isolated HIV Tat protein.

144. (Previously presented) The composition of claim 65, wherein said wild type HIV Tat protein is purified.

145. (Previously presented) The composition of claim 92, wherein said wild type HIV Tat protein is purified.

146. (Previously presented) The composition of claim 62, wherein said isolated HIV Tat protein is biologically active, as shown by (1) the ability of said isolated HIV Tat protein to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, and (2) the ability of said isolated HIV Tat protein to enter and localize in the nuclei of activated endothelial cells or dendritic cells; which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1  $\mu\text{g/ml}$ , or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1  $\mu\text{g/ml}$ , and which ability to enter and localize is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1  $\mu\text{g/ml}$  of said isolated HIV Tat protein which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy.

147. (Previously presented) The composition of claim 146, wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

148. (Previously presented) The composition of claim 147, wherein said wild type HIV Tat protein is purified.

149. (Previously presented) The composition of claim 147, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.

150. (Previously presented) The composition of claim 149, wherein said wild type HIV Tat protein is purified.

151. (Previously presented) The composition of claim 146, 147, 148, or 150 which further comprises an adjuvant.

152. (Previously presented) The composition of claim 146, 147, 148, or 150, wherein the administration is intradermal.

153. (Previously presented) The composition of claim 146, 147, 148, or 150, wherein the administration is subcutaneous.

154. (Previously presented) The composition of claim 153 which further comprises Alum.

155. (Previously presented) The composition of claim 62, wherein said isolated HIV Tat protein is biologically active, as shown by (1) the ability of said isolated HIV Tat protein to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml; and (2) the ability of said isolated HIV Tat protein to do both of the following (i) and (ii):

- (i) enter and localize in the nuclei of activated endothelial cells or dendritic cells, which entering and localizing is determined by (a) incubating activated endothelial cells or dendritic cells with up to 1 µg/ml of said isolated HIV Tat protein which is labeled with rhodamine, and (b) detecting the presence or absence of rhodamine in the activated endothelial cells or dendritic cells by fluorescence microscopy; and
- (ii) activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein is present at a concentration of up to 1 µg/ml.

156. (Previously presented) The composition of claim 155, wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

157. (Previously presented) The composition of claim 156, wherein said wild type HIV Tat protein is purified.

158. (Previously presented) The composition of claim 156, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.

159. (Previously presented) The composition of claim 158, wherein said wild type HIV Tat protein is purified.

160. (Previously presented) The composition of claim 155, 156, 157, or 159 which further comprises an adjuvant.

161. (Previously presented) The composition of claim 155, 156, 157, or 159, wherein the administration is intradermal.

162. (Previously presented) The composition of claim 155, 156, 157, or 159, wherein the administration is subcutaneous.

163. (Previously presented) The composition of claim 162 which further comprises Alum.

164. (Previously presented) The composition of claim 62 or 63, wherein said isolated HIV Tat protein comprises the cysteine rich region of HIV Tat and is in a non-oxidated form.

165. (Previously presented) The composition of claim 92, wherein said wild type HIV Tat protein is in a non-oxidated form.

166. (Cancelled)

167. (Previously presented) The composition of any of claims 147-150, wherein said wild type HIV Tat protein is in a non-oxidated form.

168. (Previously presented) The composition of any of claims 156-159, wherein said wild type HIV Tat protein is in a non-oxidated form.

169-178. (Cancelled)

179. (Previously presented) A composition comprising: an isolated HIV Tat protein in combination with a pharmaceutically acceptable carrier or excipient, wherein said isolated HIV Tat protein is in a non-oxidated form, wherein said composition is pharmaceutically acceptable for administration to a human, and wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

180. (Cancelled)

181. (Previously presented) The composition of claim 179, wherein said wild type HIV Tat protein is purified.

182. (Previously presented) The composition of claim 179, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.

183. (Previously presented) The composition of claim 182, wherein said wild type HIV Tat protein is purified.

184. (Previously presented) The composition of claim 179, 181, or 183 which further comprises an adjuvant.

185. (Previously presented) The composition of claim 179, 181, or 183, wherein the administration is intradermal.

186. (Previously presented) The composition of claim 179, 181, or 183, wherein the administration is subcutaneous.

187. (Previously presented) The composition of claim 186 which further comprises Alum.

188. (Previously presented) The composition of claim 179, wherein said isolated HIV Tat protein is conjugated to a T-helper peptide or T-helper universal epitope of Tetanus Toxoid.

189. (Previously presented) The composition of claim 179, which further comprises HIV rev, nef or gag, or an immunogenic fragment thereof.

190. (Previously presented) The composition of claim 179, which further comprises an immuno-modulant cytokine.



191. (Previously presented) The composition of claim 190, wherein said immuno-modulant cytokine is IL-12 or IL-15.

192-198. (Cancelled)

199. (Previously presented) The composition of claim 62, wherein said isolated HIV Tat protein is biologically active, as shown by (1) the ability of said isolated HIV Tat protein to activate virus replication when said isolated HIV Tat protein is added to HIV-1 infected cells, and (2) the ability of said isolated HIV Tat protein to activate the proliferation, migration, and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said isolated HIV Tat protein is present at a concentration of up to 1 µg/ml; which ability to activate is determined by (A) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml, or (B) the transactivation of HIV-1 gene expression in cells transfected with a HIV-1 promoter-reporter plasmid after the addition of said isolated HIV Tat protein at a concentration of up to 1 µg/ml.

200. (Previously presented) The composition of claim 199, wherein the isolated HIV Tat protein is a wild type HIV Tat protein.

201. (Previously presented) The composition of claim 200, wherein said wild type HIV Tat protein is purified.

202. (Previously presented) The composition of claim 200, wherein the amino acid sequence of said wild type HIV Tat protein consists of SEQ ID NO:2.

203. (Previously presented) The composition of claim 202, wherein said wild type HIV Tat protein is purified.

204. (Previously presented) The composition of claim 199, 200, 201, or 203 which further comprises an adjuvant.

205. (Previously presented) The composition of claim 199, 200, 201, or 203, wherein the administration is intradermal.

Appl. No. 09/555,534  
Attorney Docket No. 11340-003-999  
Response dated Oct. 29, 2009  
Reply to final Office Action dated April 30, 2009

206. (Previously presented) The composition of claim 199, 200, 201, or 203, wherein the administration is subcutaneous.

207. (Previously presented) The composition of claim 206 which further comprises Alum.